

Application Serial No.: 10/717,282
Amendment dated May 22, 2006
Response to Office Action dated February 21, 2006

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REMARKS

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1 - 14 are now in the case. Claims 2 and 3 have been amended as suggested by the Examiner. Applicants believe that the present amendment does not add any new matter.

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

THE 35 USC §101 AND §112, FIRST PARAGRAPH REJECTIONS

Claims 1-14 are rejected under 35 USC §101 as not supported by either a specific and substantial asserted utility or well established utility. In particular, it is asserted that the invention is directed to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance.

This rejection is respectfully traversed. Applicant respectfully submits that the rejection is contrary to both the law and the United States Patent Office's own examination guidelines. The application of these standards to biotechnology inventions is discussed in the January 5, 2001 Federal Register Notice of the United States Patent Office's Utility Examination Guidelines. Section II.B.1(c)(1) and (2) of the January 5, 2001 "Utility Examination Guidelines" states "[a]n invention has a well-established utility if a person of ordinary skill would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties...), and the utility is specific, substantial, and credible" (66 FR 4, p. 1098). Moreover, "[a] patent examiner must accept a utility asserted by an applicant unless the Examiner has sound scientific reasoning to rebut the assertion" (66 FR 4, p. 1096). To establish a *prima facie* showing of lack of utility, "the Office must ... provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing ... the PTO must do more than merely question operability - it must set forth factual reasons which would lead one of skill in the art to question the objective truth of the statement of operability" (MPEP 2107.02(IV)). In addition, 66 FR 4, p. 1096 states that:

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When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. . . . [A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient.

Upon reading the specification, one of skill in the art would appreciate that ZcytoR18 is a member of the sufficiently conserved Interleukin-17 receptor related family of proteins and would reasonably impute that same specific, substantial, and credible utility to ZcytoR18.

The Examiner has provided no evidence or scientific basis to refute the assertions of utility for the polynucleotides of the present invention. The invention indeed has a specific asserted and a well-established utility for the claimed polynucleotides that are supported by the specification. Thus, Applicant submits that the Examiner has not established a *prima facie* showing of lack of utility, because it has not provided sound scientific reasoning to rebut the assertion of utility in the application and the evidence presented by Applicant therein. In view of the Examiner's apparent failure to note and evaluate this evidence, Applicant submits that a *prima facie* showing of no specific and substantial credible utility has not been made.

For the above reasons, Applicant respectfully submits that the invention recited in claims 1-14 is useful. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are respectfully requested.

Claims 1-14 were rejected under 35 U.S.C. §112, first paragraph, "since the claimed invention is not supported by either a specific, substantial or credible utility . . . , one skilled in the art clearly would not know how to use the claimed invention." This rejection is respectfully traversed.

As discussed above, Applicant has indeed asserted a specific and well established utility for the inventions recited in claims 1-14. Claims 1-14 are indeed supported by a specific utility that is substantial and credible. Moreover, upon reading the

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specification, one of skill in the art would know how to make and use the isolated polynucleotides of the present invention without undue experimentation. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

35 USC § 112, SECOND PARAGRAPH REJECTIONS

The Examiner has rejected claims 2 and 3 under 35 USC § 112, second paragraph as failing to set for the subject matter which applicants regard as their invention. More specifically, the Examiner has noted that claim 2 is indefinite because it appears to be drawn to a polypeptide. Claim 3 is said to be indefinite for reciting "is", which can be either open or closed language.

Applicants have amended these claims as suggested by the Examiner. Accordingly, Applicants believe that the present rejections are moot and should be withdrawn.

CONCLUSION

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

Respectfully Submitted,



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Enclosures:

Amendment Fee Transmittal (in duplicate)

Customer No. 10117